IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

KIRPAL MAHAL,	)	
Plaintiff	)	
v.	)	No. 3:03-cv-411
TUSCULUM COLLEGE, JOHN DEERE HEALTH CARE, INC., and TUSCULUM COLLEGE'S MANAGED CARE HEALTH BENEFITS PLAN,	)	
Defendants	)	

MEMORANDUM OPINION

Plaintiff Kirpal S. Mahal (Dr. Mahal) filed this action pursuant to the Employee Retirement Income Security Act (ERISA), 29 U.S.C. §1001, *et seq.*, to recover benefits from defendant Tusculum College's Managed Care Health Benefits Plan (the Plan). Defendant John Deere Health Care, Inc. (JDHC), is the plan administrator for the Plan. Defendant Tusculum College is Dr. Mahal's employer.

In his complaint, Dr. Mahal contends that JDHC wrongfully denied coverage under the Plan for a microprocessor-controlled prosthetic limb following an above-the-

knee amputation of his left leg due to cancer. It is undisputed that JDHC provided Dr. Mahal with a standard prosthesis; however, Dr. Mahal contends that this device fails to restore him to the basic function lost as required by the Plan. Dr. Mahal further contends that the C-Leg by Otto Bock Health Care (the C-Leg), a microprocessor-controlled prosthesis, will restore him to the basic function lost as a result of that amputation. Defendants contend that coverage for the C-Leg was properly denied under the Plan.

This matter is presently before the court on the following motions:

(1) JDHC's motion for judgment on the administrative record [Doc. 21];

(2) Plaintiff's motion for judgment on the administrative record [Doc. 23]; and

(3) The Plan's motion for judgment on the pleadings [Doc. 24].

The issues raised have been exceptionally well briefed by the parties [*see* Docs. 22, 26, 27, 28, and 30][1], so that this matter is now ripe for adjudication. For the reasons that follow, plaintiff's motion will be denied, defendants' motions will be granted, and this action will be dismissed.

[1]In particular, the court observes that counsel for Dr. Mahal and for defendant JDHC have filed truly outstanding briefs on behalf of their respective clients.

I.

Factual Background

Dr. Mahal is an employee of Tusculum College located in Greeneville, Tennessee, where he is a Professor of Physical Education, teaching courses such as Touch and Flag Football, Soccer, Rhythm and Dance, Racquetball, Tumbling and Gymnastics, Bowling, and Badminton [*see* Administrative Record, p.0099 (hereinafter AR ___)]. Tusculum College maintains a self-funded, managed care health benefits plan for its employees and their dependents [*see* Summary Plan Description (SPD) (AR 001-48)]. As previously noted, JDHC is the named administrator of the Plan and, pursuant to the SPD, is vested with "discretionary authority to determine eligibility for benefits and to construe and interpret all terms and provisions of [the SPD]." [AR 0001, 0004, and 0038].

The Plan provides various medical benefits including coverage for prosthetic devices, specifically stating as follows:

> **Prosthetic Devices**
>
> If an injury or illness causes loss or impairment of a bodily organ, the Plan will provide benefits for replacement parts called prosthetic devices. ... Benefits are payable for prosthetic devices only to the extent that the device restores the basic function lost as a result of disease or accidental injury. Any enhancements above what are medically necessary to restore basic function will not be covered.

[AR 0023-24]. In addition to the "basic function" limitation, the Plan provides the following exclusions applicable to the Plan as a whole:

> **EXCLUSIONS APPLICABLE TO THE ENTIRE PLAN**
>
> The Plan does not provide coverage for the following:
>
> 1. Any care or treatment that is not medically necessary.
>
> ...
>
> 13. Experimental and/or investigational drugs, devices, medical treatments or procedures, including any complications arising therefrom. Experimental or investigational means:
>
> ...
>
> c. Reliable evidence shows that the consensus of opinion among experts regarding the drug, device, medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis for the patient's medical condition.
>
> Reliable evidence shall mean only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, medical treatment or procedure or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device, medical treatment or procedure.

[AR 0034 and 0036]. Finally, the Plan sets forth the following restrictions:

IMPORTANT COVERAGE RESTRICTIONS

Medical Necessity

> Benefits will be paid only for hospital, medical or other service or treatment which is medically necessary. To be medically necessary, services must meet the following criteria as determined by the attending Physician:
>
> 1. The services are consistent with generally accepted principles of medical practice for the diagnosis and treatment of the patient's medical condition; and,
>
> 2. The services are performed in the most cost-effective manner in terms of treatment, method, setting, frequency and intensity, taking into consideration the patient's medical condition.

[AR 0038].

On September 3, 2002, Dr. Mahal's left leg was amputated above the knee due to complications from cancer [AR 0054]. Subsequently, Dr. Michael J. Menz (Dr. Menz), an orthopedic surgeon in Greeneville, Tennessee, assumed Dr. Mahal's post-surgical treatment [AR 0064]. On October 29, 2002, Dr. Menz sent a letter to Hangar Prosthetics and Orthotics, Inc. (HPO) in Johnson City, Tennessee, stating specifically as follows:

. . .

> During this time, Mr. Mahal has demonstrated tremendous physical and psychological will and determination that has allowed him to successfully overcome his traumatic above knee

> amputation. Throughout the past years, he has withstood very demanding work and social schedules in which he will need a well-fitted and highly functional prosthesis.
>
> Mr. Mahal has an opportunity to benefit from a new technologically advanced knee mechanism, the Otto Bock C-leg. This knee has been designed to allow Mr. Mahal to further his independence and activities while improving his stability and security and reducing his overall energy expenditure.
>
> At this time, I feel it is medically necessary to provide Mr. Mahal with a prosthesis to include the Otto Bock C-leg. With this componentry, the patient can begin working toward his future goals and rehabilitation plans.

[AR 0064].

In response to that correspondence, HPO sent a request via facsimile on November 5, 2002, to JDHC seeking approval for the C-Leg [AR 0054]. That request notes that Dr. Mahal is "an energetic, healthy individual who is involved in a variety of activities where superior function and a positive self-image are of paramount concern." [*Id.*]. The request further notes that Dr. Mahal "requires a prosthesis that will enable him to pursue a full and active lifestyle." [*Id.*]. Attached to the request was a clinical evaluation seeking authorization for several prostheses, including a C-Leg [AR 0056-60]. The evaluation also considers Dr. Mahal's daily activities in conjunction with the benefits offered by the C-Leg [AR 0058-60]. Specifically, the request notes that Dr. Mahal requires stability in the knee unit because "he walks and stands in confined areas and in crowded public areas." [AR 0058]. Moreover, because Dr. Mahal "walks at variable

speeds" in normal day-to-day activities, he requires a knee that will "be able to automatically adjust settings to accommodate for change in gait." [*Id.*]. Additionally, the report notes that Dr. Mahal is "required to stand and ambulate while carrying items and performing tasks[,]" he is unable "to focus his concentration on controlling the stability of the knee unit." [*Id.*]. The report also notes that Dr. Mahal "routinely walks on uneven terrain/gravel, ramps and in crowded areas" so that he "requires the benefit of a knee mechanism that will provide maximum security and stability by being able to adjust to improper knee movement and gait patterns and initiate a stumble recovery feature." [AR 0059]. The report further states that Dr. Mahal regularly enters and exits a car and therefore "requires a knee that will require maximum stability and security to avoid premature flexion of the knee while initiating a deep bending motion." [*Id.*]. Finally, the report observes that Dr. Mahal "is an active walker and requires a knee mechanism that will reduce overall energy consumption allowing him to walk farther without experiencing fatigue and weariness." [*Id.*].

Based on the above patient requirements of Dr. Mahal, HPO concluded that the C-Leg was appropriate for addressing each and every one of these needs [AR 0057-60]. Among other features, the report notes that the C-Leg adjusts 50 times per second, which results in the "reduced risk of stumbling, and a more energy-efficient gait." [AR 0058]. Additionally, the C-Leg can be "optimized for all gait patterns from the very casual 'strolling' style to very aggressive 'military' movements." [*Id.*]. Moreover, the C-

Leg flex-yield rate can be "used to decelerate the prosthesis while sitting down or descending stairs and ramps." [AR 0059]. Finally, the report notes that "[p]reliminary scientific studies have suggested that the resulting gait with a C-Leg is more natural, less asymmetric and therefore more energy efficient." [AR 0060]. The total cost of the proposed C-Leg was $43,549.90 [AR 0062].[2]

Upon receiving HPO's proposal, JDHC conducted an Initial Medical Necessity Review (Initial Review) of the C-Leg. [AR 0050]. Specifically, Dr. Christine Petty, a Board certified physician, reviewed Dr. Mahal's request and determined that the Plan did not provide coverage for the C-Leg [*Id.*].

In conducting the Initial Review, Dr. Petty analyzed relevant literature regarding the C-Leg, which indicated, among other things, that the C-Leg was relatively new in the United States [AR 0169-95]. Those materials also indicated that in obtaining FDA approval to market this prosthesis, the manufacturer of the C-Leg submitted a Section 510(k) application indicating that the C-Leg was "substantially equivalent" to the manufacturer's hydraulic controlled single axis prosthesis known as the 3C1 Leg, a device

[2]This amount represents the contract rate for the C-Leg; the customary rate for this device is $61,293.00 [AR0062].

exempt from the requirements of FDA approval [AR 0170, AR 0173].[3] Significantly, the manufacturer's application with the FDA states the following:

. . .

> F. Technological Characteristics Summary
>
> The C-LEG (3C100) is substantially equivalent to Otto Bock's 3C1, a Class 1 Exempt Device according to 21 C.F.R. Part 890.3420.
>
> Differences that exist between these devices, relating to technical specifications, physical appearance and design, do not affect the relative safety and effectiveness of the C-LEG (3C100).

[AR 0173].

Additionally, among the materials reviewed by Dr. Petty was a March 2000 report by the Department of Veterans Affairs (VA) Technology Assessment Program (the VA Short Report), which had recently analyzed the existing peer-reviewed medical literature discussing microprocessor-controlled lower limb prostheses similar to the C-Leg

[3]Otto Bock's 3C1 hydraulic controlled single axis prosthesis was placed on the market prior to the date of the enactment of the 1976 Medical Device Amendment to the Food, Drug and Cosmetic Act [AR 0170, AR 0173]. Consequently, Otto Bock was not required to provide efficacy data normally required for pre-market approval application with the FDA [*id.*].

[AR 0182-92].[4] In conducting its review, the VA examined over 400 citations with abstracts [AR 0185]. The VA researchers pointed out that the C-Leg and other microprocessor-controlled prostheses are new to the United States [AR 0183, AR 0190]. Furthermore, the VA researchers found that the "published research" addressing the effectiveness of microprocessor-controlled prostheses "is a small body of work." [AR 0182, AR 0190]. Of the available published research, less than 3% of the studies represented "structured research." [AR 0182]. Even then, most of the available structured research was actually based on different microprocessor-controlled prostheses [AR 0182].[5] Significantly, the VA Short Report indicated that the majority of published articles on this topic are "purely descriptive or frankly promotional." [AR 0182].

Additionally, in reviewing the limited published articles regard microprocessor-controlled prostheses, the VA researchers expressed serious concern regarding the process utilized by the individual studies to select amputees for inclusion in

[4]The VA Short Report was prepared in response to a request from the VA's Rehabilitation Strategic Healthcare Group and "combines research results from the peer-reviewed medical literature, with findings of an assessment of a similar prosthesis conducted in the UK." [AR 0182].

[5]Most available structured research was based on a microprocessor-controlled device known as the Intelligent Prosthesis (IP), rather than the C-Leg [AR 0182]. In 1993, Blatchford and Sons Ltd. (Blatchford), a prosthetic manufacturer in the United Kingdom, introduced the IP as the first microprocessor-controlled prosthesis [AR 0173]. In 1995, Blatchford introduced a supposedly improved version fo the IP, known as the Intelligent Prosthesis Plus [AR 0173].

the articles [AR 0182, AR 0190]. Specifically, the VA researchers observed that "[t]he selective inclusion of criteria for research patients noted above undoubtedly introduce[d] bias in the study results, precluding definitive attribution of improvements in gait, energy expenditure, etc. to the computerized prosthesis." [AR 0182, AR 0190]. Moreover, despite the manufacturer's promotional statements regarding the effectiveness of the C-Leg, the VA found that "[r]esults on the potentially improved ability to negotiate uneven terrain, stairs, or inclines [were] mixed." [*Id.*]. Finally, the VA Short Report even considered the Nimmervoll Report relied upon by Dr. Mahal [AR 0184, AR0191].

Dr. Petty also reviewed the coverage policy bulletin issued by Aetna US Healthcare on December 3, 2001 (the Aetna Bulletin), regarding the C-Leg [AR 0193-95]. Specifically, Aetna's coverage policy states the following with respect to the C-Leg:

> Aetna US Healthcare does <u>not</u> cover microprocessor-controlled lower limb prostheses (Otto Bock C-Leg) because they are considered investigational because of a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness.

[AR 0193 (emphasis in original)]. In issuing its coverage position, the record reflects that Aetna reviewed the manufacturer's 510(k) FDA application, the VA Short Report discussed above, and a recent study issued by a reviewing organization in Germany [AR 0171]. With respect to the most recent German study, Aetna noted that "[s]imilar to previously published studies, this was an uncontrolled descriptive study involving a

selected group of 15 patients, reporting on their subjective assessments of the microprocessor-controlled lower limb prosthesis compared with previously fitted mechanically controlled prosthetic knee joints." [*Id.*]. Aetna concluded that, "[n]o reports on the C-Leg have been published in peer-reviewed journals to date. Available evidence can be found at the manufacturer's web page only." [AR 0172]. Therefore, Aetna considers the Otto Bock C-Leg to be investigational and denies coverage for this prosthetic device under its policies [AR 0171].

It must be noted, however, that during the Initial Review, JDHC discovered that at least one insurance carrier is providing limited coverage for microprocessor-controlled prosthetic legs such as the C-Leg [AR 0179]. Specifically, Wellmark BCBS of Iowa/South Dakota (Wellmark) issued a coverage statement in November 2002 stating that C-Leg prostheses are covered under its plans [AR 0180]. However, in order to qualify for a C-Leg prosthesis, the individual must meet six criteria, including that he or she "has successfully utilized a hydraulic knee system for at least two years." [*Id.*]. Thus, Dr. Mahal would not qualify at this time, even under Wellmark's policy.

Based on the above information, and based on Dr. Petty's determination that the Plan did not provide coverage for the C-Leg, JDHC issued a denial letter on November 11, 2002, to Dr. Mahal in which it stated that a Board certified physician had reviewed his request for payment authorization and that his request was denied for the following reason:

> John Deere Health's medical necessity criteria has not been established for the above item as they are considered investigational because of a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness.

[AR 0068].[6] The denial letter also informed Dr. Mahal that he could appeal the decision by requesting and submitting an Enrollee Appeal form. [*Id.*].

On November 19, 2002, Dr. Menz sent a letter to JDHC in an effort to determine what criteria were used for the prosthesis denial [AR 0217]. Apparently, Dr. Menz never received a response, so he sent a second letter to JDHC on December 3, 2002 [AR 0225]. In that letter, Dr. Menz indicated that he had repeatedly attempted to contact someone at JDHC who could explain the criteria for the C-Leg denial [*id.*]. Dr. Menz noted that Dr. Mahal had not yet been equipped with any prosthesis and that he is "complaining that his only healthy right knee is becoming painful with stress on the leg." [*Id.*]. Dr. Menz then opined that he was "in favor of expediting the process of fitting [Dr. Mahal] with the C-Leg." [*Id.*]. Finally, Dr. Menz requested that JDHC send him the criteria used for the denial [*id.*].

[6]JDHC sent similar denial letters to Dr. Menz and to Hangar on that same date [AR 0070-71].

Dr. Mahal also had the same concern about JDHC's criteria. On December 11, 2002, Dr. Mahal sent a letter to JDHC indicating that, although he had received his appeal form, he did not receive an explanation of the criteria used for the denial which he needed to "expedite [his] appeal." [AR 0220]. On December 18, 2002, Dr. Petty responded:

. . .

> I have attempted to contact you several times (11-25-02, 11-26-02 and 11-27-02) to discuss your concerns about non-coverage for the C-leg. JDH does not have "criteria" regarding C-legs, as the device is non-payable. We do, however, have a position statement and rationale for our decision to not cover the C-leg which is enclosed.
>
> There is a lack of controlled studies to show that the C-leg is clinically superior than a standard prosthetic leg. In addition, there have been no studies/reports published in peer-reviewed journals supporting the use of this device. The only available evidence can be found at the manufacturer's web page. Because of the lack of scientific evidence and peer-reviewed medical literature, JDH considers the C-leg to be investigational. We understand that some patient's [sic] may view this as a preference to a standard prosthetic, however due to the lack of scientific evidence to support its use, we are unable to evaluate this for medical necessity.
>
> If you have any additional literature which you feel may alter this decision, you may submit this to my attention or if you wish to speak to me in person please call my secretary. ... If you wish to appeal this decision, the process for such an appeal is outlined in your contract language under the heading Complaint Procedures and may be initiated by contacting the Customer Service Department at ... .

[AR 0222].

On December 31, 2002, Dr. Mahal wrote Dr. Petty, informing her that he had not received any enclosure with her previous correspondence as indicated [AR 0092]. That enclosure was, of course, the position statement and rationale for JDHC's decision not to cover the C-Leg [*id.*]. Additionally, Dr. Mahal informed Dr. Petty regarding his anticipated 75- minute presentation on Yoga and the fact that he would be teaching Tennis during the Spring Semester [*id.*]. Dr. Mahal concluded that he was indeed a "very special person" and that "fitting [him] with a C-Leg could be beneficial to John Deere both financially and for its image." [*Id.*].

On January 8, 2003, Dr. Petty again wrote to Dr. Mahal indicating that his request for the C-Leg remains denied [AR 0083]. Additionally, Dr. Petty enclosed the position statement by JDHC on the Otto Bock C-Leg, which contains the "scientific evidence and rationale for our position on this device." [*Id.*].[7] Finally, Dr. Petty provided Dr. Mahal with information regarding the procedure for his anticipated appeal of that denial [*id.*].

On January 25, 2003, Dr. Mahal formally appealed the initial denial [AR 0097].[8] Attached to his appeal was an extensive "Request for Pre-Authorization" setting

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[7]The attachment appears to be set forth at AR 0084-91.

[8]Dr. Mahal's initial appeal is referred to in the Administrative Record as a "Level 1" appeal [AR 0269].

forth a plethora of reasons why the C-Leg should be approved [AR 0368-74]. In essence, the request documents all aspects of Dr. Mahal's physically demanding employment and active social life and details the benefit of the C-Leg as applied to his lifestyle [*id.*].

On January 29, 2003, JDHC's Vice President of Medical Management sent correspondence to Dr. Mahal apologizing for the confusion and admitting that JDHC does not have a formalized written position statement [AR 0246].[9] This correspondence further states as follows:

. . .

> From the materials sent earlier, the Virginia Technology Assessment found mixed results in negotiation of uneven terrain, stairs or inclines. They also found that the evidence of effectiveness of the Otto Bock C-leg to be limited. There have been no reports on the C-leg published in peer-reviewed journals. The only evidence is found on the manufacturer's web page. Based on the review of the literature, there is a lack of evidence that the C-leg is superior and is considered investigational.

[*Id.*].[10]

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[9]For whatever reason, the copy of this letter in the Administrative Record has been "blacked out" with respect to the recipient as well as the signature of the JDHC official holding this particular title. Nevertheless, it appears that this letter was sent to Dr. Mahal.

[10]According to Dr. Mahal, the problem with uneven terrain, stairs and inclines was with the "Intelligent Prosthesis," a British prosthesis that is not as advanced as the C-Leg [AR 0258].

On January 31, 2003, JDHC acknowledged receipt of Dr. Mahal's appeal and documentation and informed Dr. Mahal that he would be notified of JDHC's decision within 15 calendar days [AR 0168]. Pursuant to the Plan, JDHC assigned Dr. Mahal's appeal to Dr. Deepak Ahuja, a Vice President of Medical Management for JDHC and a Board certified physician in Internal Medicine [AR 0079 and AR 0280]. In conducting his review, Dr. Ahuja reviewed Dr. Mahal's medical records and all documentation considered during the Initial Review [AR 0269 and AR 0280].

After reviewing Dr. Mahal's appeal, Dr. Ahuja ultimately upheld JDHC's initial denial [AR 0280]. On February 14, 2003, JDHC notified Dr. Mahal that a Board certified physician in Internal Medicine[11] had reviewed his appeal and upheld JDHC's initial denial of payment authorization for the C-Leg [*id.*]. That letter specifically stated as follows:

> The decision was made to uphold the denial of payment authorization for an Otto Bock C-Leg. This was based on there [sic] is no published literature to document an added benefit of the C-Leg over standard prostheses, and this is supported by the FDA approval of the C-Leg as "substantially equivalent". We have sent your appeal to an outside review agency for an independent review. We have not received a response as of this date.

[*Id.*].

[11]Obviously, this physician was Dr. Ahuja, although he is not mentioned specifically by name in that correspondence [*see* AR 0079; *see also* Dr. Ahuja's affidavit filed as Exhibit A to Doc. 29].

The record reflects that the independent peer review organization chosen by JDHC to conduct this review of Dr. Mahal's case was Medical Care Management Corporation, LLC (MCMC), located in Boston, Massachusetts, and that information was sent to that organization by JDHC on February 11, 2003 [AR 0239-63 and AR 0283]. On February 20, 2003, six days after JDHC sent its second denial letter, JDHC received MCMC's Peer Review Analysis prepared in connection with Dr. Mahal's request for payment authorization [AR 0266-68]. In particular, Dr. Leela Rangaswamy, a Board certified physician in Orthopedic Surgery, performed the foregoing independent peer review [AR 0268]. In conducting her review, Dr. Rangaswamy considered JDHC's referral form, the Aetna Bulletin, Wellmark's policy statement, a video on the C-Leg, promotional material from the manufacturer, and Dr. Mahal's medical records [AR 0266]. Additionally, Dr. Rangaswamy discussed the C-Leg with the prosthetist she regularly uses in treating her patients who are amputees [*id.*]. Based on her review, Dr. Rangaswamy concluded that "[t]here are no indications for coverage of this component." [*Id.*]. Moreover, Dr. Rangaswamy noted that Dr. Mahal "is not one of the individuals who would meet the criteria for this component ... ." [*Id.*]. Dr. Rangaswamy further stated as follows:

> At present the C-LEG is not the accepted standard of care for prosthetic knees. It is not the most appropriate and least intensive level of care, since it is still investigational and the purposes of a prosthetic knee can be met in other ways. At present there is no definitive data on how to match the patient with the most appropriate prosthesis for the wearer's level of

> activity for daily living. The components used are usually influenced by the desires of the patient, often in relation to their recreational activities, coverage available and the bias of the prosthetist. At present the studies contain small samples and essentially discusses [sic] individual knees in case reports.

[AR 0267-68].

On February 24, 2003, Dr. Petty informed Dr. Mahal that "limited effectiveness" means "a lack of sufficient evidence in the published peer-reviewed medical literature substantiating [the C-Leg's] effectiveness." [AR 0282]. On February 28, 2003, Dr. Mahal requested information pertaining to other C-Leg approvals by JDHC [AR 0335-6]. On March 3, 2003, JDHC responded by informing Dr. Mahal that prior requests for C-Legs, "whether they were granted or denied, had no bearing upon the decision made in this case." [AR 0337].

After receiving JDHC's Level 1 denial letter and the peer review analysis of Dr. Rangaswamy, Dr. Mahal filed, on April 12, 2003, a Level 2 appeal with JDHC contesting its decision [AR 0343]. Dr. Mahal also submitted three peer-reviewed articles specifically addressing the C-Leg, as well as other documents for review in connection with his Level 2 appeal [AR 0343-74]. Dr. Mahal then contacted JDHC two days later on April 14, 2003, by telephone requesting that his appeal be placed on "hold" until it received his "revised request" which would be sent no later than April 28 [AR 0376]. Dr. Mahal confirmed that telephone request in writing [*id.*]. On April 15, 2003, JDHC granted

Dr. Mahal's request for an extension, allowing him until April 28 to receive any materials to support his Level 2 appeal [AR 0377].

On April 17, 2003, JDHC notified Dr. Mahal that his appeal would again be sent to MCMC, the independent reviewing agency previously utilized by JDHC in this case, which "has no direct financial interest in the appeal being reviewed." [AR 0378]. On April 29, 2003, Dr. Mahal wrote to JDHC, indicating that he had mailed his revised appeal to it on April 24 to meet the April 28 deadline [AR 0381]. Dr. Mahal was also concerned that because JDHC's letter regarding the Level 2 appeal was dated April 17, JDHC might not have provided all necessary documents to MCMC for a complete review [*id.*].

It now appears from JDHC's supplement to the Administrative Record that all of these documents were forwarded to MCMC in connection with its second external peer review [AR 0836-1004]. The supplemented record reflects that on April 21, 2003, and on April 29, 2003, JDHC forwarded, via UPS courier, the other information submitted by Dr. Mahal to JDHC [AR 0836]. More specifically, JDHC forwarded the peer-reviewed articles [AR 0991-97], Dr. Mahal's medical records [AR 0963-65], Dr. Menz's December 3, 2002, letter to JDHC [AR 0876], the VA Technology Assessment Program short report [AR 0895-905], Dr. Mahal's self-prepared "Request for Pre-Authorization" [AR 0968-74], the clinical evaluation by Hangar Prosthetics [AR 0841-50], and certain excerpts from the

Plan [AR 0998-1004]. It must be emphasized that the portions of the Plan provided to MCMC included those dealing with prosthetic devices, exclusions applicable to the entire Plan, and the Plan's medical necessity criteria [AR 0998-1004].

On May 5, 2003, Dr. F. Daniel Kharrazi, a Board certified physician in Orthopedic Surgery, issued a second Peer Review Analysis in connection with Dr. Mahal's appeal for coverage of the C-Leg [AR 0385-87]. In conducting his analysis, Dr. Kharrazi was asked to determine whether there was sufficient evidence from peer-reviewed medical literature to substantiate the claimed improved effectiveness of the C-Leg over standard prostheses [AR 0385]. After reviewing all of the information set forth above, including that forwarded by Dr. Mahal, Dr. Kharrazi concluded that "[t]here is not sufficient evidence from peer reviewed medical literature to substantiate an improved effectiveness from the otto bock C-leg." [*Id.*]. Dr. Kharrazi's conclusion was based in part upon the C-Leg manufacturer's 510k FDA application, which indicated that the C-Leg was "substantially equivalent" to its previously approved standard prosthesis [AR 0386]. Moreover, Dr. Kharrazi commented that the VA found the evidence supporting the effectiveness of the C-Leg to be "limited." [*Id.*]. Dr. Kharrazi concluded:

> As a result, this prosthesis [the C-Leg] is considered investigational and experimental and should not be covered. Recommendation is for the denial of the prosthesis.

[AR 0386-87].

Based on the foregoing independent review, JDHC sent Dr. Mahal a letter on May 7, 2003, upholding the initial denial, stating specifically as follows:

. . .

> The decision was made to uphold the denial of payment authorization for an Otto Bock C-leg. This was based on the reviewers [sic] opinion that there is not sufficient evidence from peer reviewed medical literature to substantiate an improved effectiveness from the Otto Bock C-leg compared to a conventional prosthesis. ... Your benefit plan pays for prosthetic devices only to the extent that the device restores the basic function lost as a result of disease or accidental injury. Any enhancement above what is medically necessary to restore basic function will not be covered. ...

[AR 0390]. That letter also informed Dr. Mahal that he had the right to bring a civil action pursuant to ERISA [*id.*].

On May 27, 2003, Dr. Mahal wrote to JDHC asking how that organization defined "Basic Function" and whose "basic function" was at issue. [AR 0490]. Dr. Mahal further noted that, "[a]ll of the above requested information is crucial for me in further preparation of my appeal." [*Id.*]. On June 9, 2003, Dr. Mahal wrote to JDHC inquiring whether the denial mentioned in its May 7, 2003, correspondence meant that he had exhausted all of JDHC's internal appeals process [AR 0494]. On June 19, 2003, JDHC responded that Dr. Mahal had indeed done so [AR 0496]. JDHC also wrote to Dr. Mahal

the very next day, June 20, informing him that "[b]asic function is being able to walk." [AR 0534].

On August 7, 2003, plaintiff filed this lawsuit [*see* Doc. 1]. On September 22, 2003, JDHC approved Dr. Mahal's request for a standard prosthesis [AR 0829]. The total cost for that device was $22,838.40 [AR 0824].

II.

Standard of Review

This action seeking a review of the denial of plaintiff's benefits is governed by ERISA, 29 U.S.C. § 1132(a)(1)(B), which provides as follows:

> A civil action may be brought by a participant or beneficiary to recover benefits due to him under the terms of his Plan, to enforce his rights under the terms of the Plan, or to clarify his rights to further benefits under the terms of the Plan.

In *Wilkins v. Baptist Healthcare Systems*, 150 F.3d 609, 617-20 (6th Cir. 1998) (Gilman, J. concurring and speaking for the majority of the panel), the Sixth Circuit established guidelines under which district courts must adjudicate ERISA cases brought before them for judicial review. The Sixth Circuit explained that using summary judgment as a tool for the adjudication of ERISA cases does not properly comport with the purpose of

summary judgment. *Id.* at 619. Because the role of a district court in ERISA matters is not to determine whether issues of fact exist for trial, but to review the administrative record before it, district courts should more properly characterize their role in such proceedings as encompassing elements of both bench trials and summary judgments. *Id.* at 619-20. Following these guidelines, the district court proceeds by making adjudications on both fact and law as would occur in a bench trial while handling the matter in an expedited fashion resembling summary judgment. *Id.*

Furthermore, *Wilkins*, following Supreme Court precedent, dictates this court's standard of review in ERISA matters. Under *Wilkins*, this court has two possible standards of review. If the trustees of an employee benefits plan do not have discretion to determine eligibility for benefits or to construe the terms of the Plan, this court is required to undertake a *de novo* review of the administrators' decision. *Id.* at 613. On the other hand, where a benefits plan vests discretion with the administrators, this court may only disturb the administrators' decision if it finds the basis of such a decision to be arbitrary and capricious. *Id.* at 616 (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989)). Significantly, regardless of the standard of review applied to the administrators' decision, "in an ERISA claim contesting a denial of benefits, the district court is strictly limited to a consideration of the information actually considered by the administrator." *Killian v. Healthsource Provident Admin., Inc.*, 152 F.3d 514, 522 (6th Cir. 1998) (citing *Perry v. Simplicity Eng'g*, 900 F.2d 963, 966 (6th Cir. 1990)).

Here, the Plan states as follows:

> **Discretionary Authority of JDHC**
>
> JDHC has discretionary authority to determine eligibility for benefits and to construe and interpret all terms and provisions of this document. JDHC may delegate its discretionary authority to another person, partnership, corporation or other legal entity.

[AR 0038]. Based on this unambiguous language, the parties are in agreement that the appropriate standard of judicial review in this case is the arbitrary and capricious standard [*see* Doc. 22, pp.12-13 and Doc. 30, p.16]. The court likewise agrees.

Therefore, the issue now before this court is whether the decision of the Plan Administrator to deny Dr. Mahal a C-Leg constitutes an arbitrary and capricious act based upon the administrative record. "When it is possible to offer a reasoned explanation, based on the evidence, for a particular outcome, that outcome is not arbitrary and capricious." *Spangler v. Lockheed Martin Energy Systems, Inc.*, 313 F.3d 356, 361 (6th Cir. 2002) (quoting *Davis v. Kentucky Finance Cos. Retirement Plan*, 887 F.2d 689, 693 (6th Cir. 1989) (internal quotations and citations omitted)).

III.

Analysis

This ERISA case is somewhat unusual because the plaintiff has not been denied a benefit by the plan administrator; rather, he has been denied a specific type of benefit. Here, JDHC did not deny Dr. Mahal a prosthetic - instead, it provided him with a standard hydraulic prosthesis valued at $22,838.40, as opposed to the microprocessor C-Leg valued at $43,549.90, which Dr. Mahal had requested.

Dr. Mahal claims that JDHC's decision in denying him the C-Leg was arbitrary and capricious. In support of his position, Dr. Mahal relies on a number of actions taken by JDHC beginning with its Initial Review and concluding with its Level 2 appeal. It must be underscored, however, that "[t]he ultimate issue in an ERISA denial of benefits case is not whether discrete acts by the plan administrator are arbitrary and capricious but whether its ultimate decision denying benefits was arbitrary and capricious." *Spangler*, 313 F.3d at 362. In the court's view, while some of plaintiff's grievances about the information he received from JDHC may have merit, his underlying complaint regarding JDHC's ultimate decision totally evaporates in light of the clear language of the Plan and JDHC's careful consideration of all of the information submitted to it in evaluating the merits of the C-Leg *vis-a-vis* a standard prosthetic leg.

The record reflects that Dr. Mahal's quest to receive a C-Leg began on a positive note. Dr. Mahal's treating physician, Dr. Menz, opined on October 29, 2002, that it was "medically necessary to provide Mr. Mahal with a prosthesis to include the Otto

Bock C-leg." [AR 0064]. This statement by Dr. Menz was consistent with the Plan which states, "Your Network Physician is best qualified to determine what services are medically necessary for Your care." [AR 0014]. Dr. Menz' opinion was also necessary to satisfy the "Medical Necessity" component of the COVERAGE RESTRICTIONS of the Plan. Again, that provision states as follows:

> Benefits will be paid only for hospital, medical or other service or treatment which is medically necessary. To be medically necessary, services must meet the following criteria as determined by the attending Physician:
>
> 1. The services are consistent with generally accepted principles of medical practice for the diagnosis and treatment of the patient's medical condition; and
>
> 2. The services are performed in the most cost-effective manner in terms of treatment, method, setting, frequency and intensity, taking into consideration the patient's medical condition.

[AR 0038]. However, it must be emphasized that Dr. Menz undertook no cost benefit analysis whatsoever with respect to the C-Leg as opposed to a standard prosthetic device.

One other observation must be made at this juncture. It is not surprising that Dr. Menz recommended the C-Leg for Dr. Mahal. In view of the amount of information which Dr. Mahal supplied to JDHC regarding the C-Leg throughout his various appeals, it is obvious that Dr. Mahal had extensively researched the C-Leg and strongly believed in the benefits of that device as opposed to a standard prosthetic device. Moreover, the

record clearly indicates that Dr. Mahal is an exceptionally fit individual, given his level of physical activity and the fact that he taught a number of physically demanding classes at Tusculum College. Moreover, Dr. Mahal indicated to Hangar that he hoped to be able to engage in such activities as "bicycling, bowling, badminton, racquetball, jogging, aerobics, tennis, table tennis, and walking at variable cadence ... ." [AR 0057]. Against this background, Dr. Menz believed that Dr. Mahal needed more than a standard prosthetic device to reach these goals.

After receiving Dr. Menz' letter and Hangar's proposal, JDHC conducted the Initial Review, utilizing Dr. Petty, a Board certified physician. Dr. Petty reviewed considerable literature regarding the C-Leg, finding that the C-Leg was relatively new in the United States [AR 0169-95]. Additionally, the materials reviewed by Dr. Petty indicated that the manufacturer of the C-Leg submitted a Section 510(k) application in obtaining FDA approval to market this prosthesis which reflected that the C-Leg was "substantially equivalent" to the manufacturer's hydraulic controlled single axis prosthesis known as the 3C1 Leg, a device exempt from the requirements of FDA approval [AR 0170, AR 0173]. However, because the 3C1 hydraulic controlled single axis prosthesis was placed on the market prior to the date of the enactment of the 1976 Medical Device Amendment to the Food, Drug & Cosmetic Act, Otto Bock was not required to provide efficacy data normally required for pre-market approval application with the FDA [AR 0170, AR 0173]. Even more significantly, the manufacturer specifically stated in its FDA

application that "differences that exist between [the C-Leg and the 3C1 Leg] do not affect the relatively safety and effectiveness of the C-Leg (3C100)." [AR 0173]. Obviously, the manufacturer's statement in its FDA application undercuts the proposition that the C-Leg is a more effective prosthesis.

Other materials reviewed by Dr. Petty include the VA Short Report and the coverage policy issued by Aetna U.S. Healthcare on December 3, 2001, regarding the C-Leg. The court, like Dr. Petty, has carefully reviewed those items and they contain both positive and negative comments about the C-Leg. They certainly do not lead to the conclusion that the C-Leg is a superior prosthetic device. This court has previously set forth some of the specific statements in the VA Short Report and in Aetna's Bulletin, and those statements need not be repeated again. The court would underscore, however, the fact that the VA report indicated that the majority of published articles on microprocessor controlled prosthesis are "purely descriptive or frankly promotional." [AR 0182]. Moreover, Aetna's coverage policy states, with respect to the C-Leg, that they are not covered because they are considered "investigational because of a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness." [AR 0193].

Based on the above information, and based on Dr. Petty's determination that the Plan did not provide coverage for the C-Leg, JDHC issued a denial letter on November

11, 2002, to Dr. Mahal in which it stated that a Board certified physician had reviewed his request for payment authorization and that his request was denied for the following reason:

> John Deere Health's Medical Necessity criteria has not been established for the above item as they are considered investigational because of a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness.

[AR 0068]. Dr. Mahal now complains that this letter is somewhat confusing regarding the criteria used to deny him coverage for the C-Leg. The court disagrees.

This initial letter sets forth three bases for denial: (1) lack of "medical necessity;" (2) the C-Leg is considered "investigational;" and (3) "lack of sufficient evidence in the published peer-reviewed medical literature substantiating [the C-Leg's] effectiveness." Again, the Plan clearly does not provide coverage for any treatment that is "not medically necessary" nor does it provide coverage for "investigational ... devices ... ." [AR 0034 and AR 0036]. While the term "medically necessary" is not defined in the Exclusions portion of the Plan, the term "investigational" is. A device is deemed "investigational" if "reliable evidence," as defined by the Plan, establishes that "the consensus of opinion among experts regarding the ... device ... is that further studies or clinical trials are necessary to determine ... its efficacy, or its efficacy as compared with the standard means of treatment ... for the patient's medical condition." [AR 0036]. The Plan then defines "reliable evidence" as follows:

> Published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, medical treatment or procedure or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device, medical treatment or procedure.

[*Id.*].

In the court's view, the VA Short Report and the Aetna Bulletin constitute "reliable evidence" as defined under the Plan. Specifically, the VA Short Report is a published report produced in response to a request from the VA's Rehabilitation Strategic Healthcare Group [AR 0182, AR 0185]. The report reviewed approximately 400 citations with abstracts and conducted a "detailed review" of 36 of the 400 abstracts [*id.*]. Moreover, the VA report directly addressed the effectiveness of the C-Leg prosthesis as compared to standard hydraulic or pneumatic prosthetic limbs [AR 0182, AR 0190-91]. The Aetna Bulletin also examined, in detail, the peer-reviewed medical literature addressing the overall effectiveness of the C-Leg as compared to standard prosthesis [AR 0171-72]. The court is of the opinion that the Aetna Bulletin constitutes "the written protocol ... of another facility studying substantially the same ... device," *i.e.*, the Otto Bock C-Leg [AR 0036]. Thus, both the VA Report and the Aetna Bulletin constitute "reliable evidence" as that term is defined in the exclusionary language of the Plan.

Even more significantly, the detailed findings set forth in the VA Report and in the Aetna Bulletin provide substantial support for JDHC's conclusion that, due to the lack of published peer-reviewed medical literature addressing the overall effectiveness of the device, the C-Leg prosthesis is "investigational" and not a covered prosthesis under the Plan. It is particularly telling that the VA noted that the "published research" addressing the efficacy of microprocessor controlled prostheses "is a small body of work." [AR 0182, AR 0190]. Further, the VA researchers described most of the articles as "purely descriptive or frankly promotional." [AR 0170, AR 0182, and AR 0190]. More specifically, despite the manufacturer's promotional claims, the VA found that "[r]esults on the potentially improved ability to negotiate uneven terrain, stairs, or inclines [were] mixed." [AR 0182, AR 0190].

Dr. Petty was not the only physician to opine that the C-Leg was not covered by the Plan. After Dr. Mahal appealed the initial decision, Dr. Ahuja, a Board certified physician in Internal Medicine, conducted an extensive review of Dr. Mahal's medical records and all documentation considered during the Initial Review [AR 0269 and AR 0280]. Dr. Ahuja ultimately upheld JDHC's initial denial indicating in his letter that there is "no published literature to document an added benefit of the C-Leg over standard

prosthesis, and this is supported by the FDA approval of the C-Leg as 'substantially equivalent.'" [AR 0280].[12]

Moreover, after receiving Dr. Mahal's Level 1 appeal, JDHC sought the additional advice of MCMC, an independent review organization, concerning the issue of coverage for the C-Leg. On February 20, 2003, JDHC received Dr. Rangaswamy's peer review analysis [AR 0266-68]. Dr. Rangaswamy explained as follows:

> At present, the C-LEG is not the accepted standard of care for prosthetic knees. It is not the most appropriate and least intense level of care, since it is still investigational and the purposes of a prosthetic knee can be met in other ways.

[AR 0266]. Notably, Dr. Rangaswamy reached the foregoing conclusion after discussing the coverage issue with a prosthetist she regularly uses in treating her patients who are amputees [*id.*]. This statement by Dr. Rangaswamy fully supports JDHC's conclusion that the C-Leg is not medically necessary. Again, the Plan specifically states as follows:

> 1. The services are consistent with generally accepted principles of medical practice for the diagnosis and treatment of the patient's medical condition;

[12]The court would note that even though Dr. Petty and Dr. Ahuja are employed by JDHC, JDHC does not insure the Plan. [AR 0004]. Rather, Tusculum College is responsible for paying the benefits provided pursuant to the Plan [*id.*]. Thus, JDHC is not a financially interested party in the administration of the Plan.

. . .

[AR 0038].

The fourth physician to review Dr. Mahal's appeal, Dr. Kharrazi, a Board certified physician in Orthopedic Surgery, also reached a similar conclusion. After reviewing all of the information previously reviewed by the other physicians, as well as additional information forwarded by plaintiff [AR 0836-1004], Dr. Kharrazi concluded that "[t]here is not sufficient evidence from peer-reviewed medical literature to substantiate an improved effectiveness from the otto bock C-leg." [AR 0385]. As previously noted, Dr. Kharrazi's conclusion was based in part upon the C-Leg manufacturer's 510(k) FDA application, which indicated that the C-Leg was "substantially equivalent" to its previously approved standard prosthesis [AR 0386]. Dr. Kharrazi also noted that the VA found that the evidence supported the effectiveness of the C-Leg to be "limited" [*id.*]. Thus, Dr. Kharrazi concluded that the C-Leg is "investigational and experimental and should not be covered." [AR 0386-87].

The record therefore reflects that Dr. Mahal's request was reviewed by JDHC on four occasions by four different physicians. Dr. Mahal contends that JDHC constantly changed the basis for its denial because JDHC was "unsure about what would be the rationale for its decision." [Doc. 30, p.17]. Nevertheless, the record reflects otherwise.

JDHC set forth in its initial denial that the C-Leg was "investigational" because of "a lack of sufficient evidence in the published peer-reviewed medical literature substantiating their effectiveness." [AR 0068]. Although Dr. Petty did not specifically use that term in her very short report to JDHC [AR 0050], Dr. Petty did state in follow-up correspondence to Dr. Mahal that the C-Leg was "investigational" "[b]ecause of the lack of scientific evidence and peer-reviewed medical literature ... ." [AR 0222]. A further review of Dr. Petty's letter indicates that her explanation is fully consistent with JDHC's position. Likewise, Dr. Rangaswamy and Dr. Kharrazi also employed the term "investigational." [AR 0267, AR 0386].

Dr. Mahal contends that JDHC's reference to "peer-reviewed" medical literature in these denial letters is inconsistent with the definition of "investigational" contained in the Plan [*see* Doc. 30, p.18]. However, the Plan specifically refers to "reliable evidence" and defines the foregoing term as "published reports and articles" in the "authoritative medical and scientific literature." [AR 0034-36]. In the court's review, "authoritative medical and scientific literature" includes published peer-reviewed medical literature that addresses the overall effectiveness of the C-Leg. Most certainly, this definition does not encompass newspaper articles, fitness reports or self-serving documents created by a Plan member, such as Dr. Mahal's "Appeal to Pre-Authorized Payment" [AR 0098-103].

Dr. Mahal further contends that JDHC improperly defined the term "basic function" and only did so after the final denial was rendered [*see id.*, pp.11, 18]. However, the court is of the opinion that JDHC's interpretation of the term "basic function" was rational and consistent with a commonsense understanding. Moreover, JDHC's failure to provide Dr. Mahal with its definition of "basic function" at the time of its final denial does not render JDHC's decision arbitrary and capricious.

Again, the Plan provides various medical benefits including coverage for prosthetic devices, specifically stating as follows:

Prosthetic Devices

> ... Benefits are payable for prosthetic devices only to the extent that the device restores the basic function lost as the result of disease or accidental injury. Any enhancements above what are medically necessary to restore basic function will not be covered.

[AR 0024]. Although JDHC relied upon separate enumerated exclusions in the Plan in denying coverage, *i.e.*, the medical necessity exclusion and the exclusion regarding investigational devices, JDHC also relied upon the above coverage limitation regarding the restoration of "basic function" in its final denial letter of May 7, 2003 [AR 0390]. Upon inquiry by Dr. Mahal as to the definition of "basic function," JDHC informed him that it interpreted basic function as "being able to walk." [AR 0534].

The term "basic function" is not defined in the policy. Nevertheless, the term "basic" is limiting in nature and denotes a minimum level of function such as walking, standing, or sitting. The court agrees with JDHC that strenuous activities such as running or jumping would fall outside of the context of "basic function." The court rejects plaintiff's notion that the term "basic function" must be determined on a case-by-case basis depending on the physical abilities of the individual member of the Plan. If that broader definition were accepted, then the language in the Plan would have no limitation whatsoever because "basic function" would mean "full, pre-injury function." Dr. Mahal's suggested interpretation of the term "basic function" would be more accurately defined as "maximum function." In the court's view, such a construction of the policy is illogical and not supported by the language of the Plan. Even though the court is somewhat surprised that JDHC did not initially rely on the definition of "basic function" in rejecting Dr. Mahal's request for the C-Leg, that is not to suggest that the Plan was arbitrary and capricious in doing so later. Furthermore, to the extent that the term "basic function" is ambiguous, the Sixth Circuit has held that it will "grant plan administrators who are vested with discretion in determining eligibility for benefits great leeway in interpreting ambiguous terms." *Moos v. Square D Co.*, 72 F.3d 39, 42 (6th Cir. 1995) (citation omitted). In this case, even allowing the plan administrator some leeway to interpret the term "basic function," the court concludes that JDHC's interpretation of "basic function" with respect to a prosthetic leg to encompass walking is indeed rational and therefore not arbitrary and capricious.

Finally, in ruling as it has, the court cannot ignore the fact that there is no evidence in this record that any other benefit plan would have provided Dr. Mahal with a C-Leg under these circumstances. The record does indicate that one plan, Wellmark, did issue a coverage statement in November 2002 stating that C-Leg prostheses are covered under its plans [AR 0180]. Yet, Dr. Mahal would not qualify under those plans because he would have to "successfully utilize [] a hydraulic knee system for at least two years." [*Id.*]. In other words, even Wellmark would have rejected Dr. Mahal's request to be fitted immediately with a C-Leg.

IV.

Conclusion

In sum, the court finds that JDHC's decision to deny Dr. Mahal coverage for the C-Leg was not arbitrary and capricious. To the contrary, the court finds that the C-Leg is excluded because JDHC rationally concluded that it was not "medically necessary" and because it is still "investigational." Moreover, the court finds that JDHC's decision that a standard prosthetic leg will restore "basic function" to Dr. Mahal is rational.

Finally, in ruling as it has, the court takes no pleasure whatsoever in denying Dr. Mahal the use of the prosthetic leg which he so earnestly seeks. Without question, Dr. Mahal is an extraordinarily fit and determined individual. It may very well be that the C-

Leg would be a perfect marriage for Dr. Mahal, allowing him to engage in physical activities the ordinary recipient would be unable to achieve for a variety of reasons. Nevertheless, the question for this court is whether the plan administrator's decision in denying him that particular prosthesis is arbitrary and capricious based on a review of this Administrative Record and based on the plain language of the Plan. After engaging in that analysis, the court finds that defendant's motions on the Administrative Record must be granted and the plaintiff's motion must be denied.

Enter judgment accordingly.

s/ James H. Jarvis
UNITED STATES DISTRICT JUDGE